



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1994-D-0007]

Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is considering revising the guidance entitled "Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds," and is seeking comments on this guidance before revisions are made.

DATES: Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Xin Li, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6863, xin.li@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

One of the key objectives of Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds (GFI #80) is to help sponsors design efficacy studies to support the submission of Food Additive Petitions (FAPs) for food additives intended for anti-Salmonella use in food for animals. We would like to revise GFI #80 because science, technology, and FDA policy have changed since this guidance was last revised.

GFI #80 currently addresses only chemical food additives intended to maintain feeds or feed ingredients Salmonella-negative. We intend to expand the scope of this guidance to address other categories of food additives beyond chemical food additives, and to cover all food for animals, including pet food.

Before we revise the content of GFI #80 we intend to consider your answers to the following questions:

1. What intended technical effects can we expect to see in FAPs submitted to FDA for anti-Salmonella use of the food additives in food for animals?
2. How should efficacy studies be designed for the intended technical effects described in your response to question 1?
3. Should experimental lots of animal food used in both laboratory and field studies be Salmonella-negative, but not sterile, prior to inoculation?

4. What inoculation levels of Salmonella are appropriate for experimental lots of animal food used in laboratory and field studies? Please justify your comment with scientific evidence.

5. What methods should be used to inoculate experimental lots of animal food used in laboratory and field studies?

6. What sampling criteria should be used to provide statistical confidence that Salmonella will be captured among samples collected? Please justify your comment with scientific evidence.

7. What methods should be used to enumerate the level(s) of Salmonella in animal food?

8. What are the key elements for designing field studies?

9. What are the difficulties faced by sponsors when designing and conducting field studies?

10. What types of facilities are available to conduct field studies?

Electronic versions of GFI #80 are in the docket at <http://www.regulations.gov> and on FDA's Web site at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 5, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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